# General

## Guideline Title

Final recommendation statement: celiac disease: screening.

## Bibliographic Source(s)

Final recommendation statement: celiac disease: screening. [internet]. Rockville (MD): U.S. Preventive Services Task Force (USPSTF); 2017 Mar [7 p]. [28 references]

## Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

# NEATS Assessment

National Guideline Clearinghouse (NGC) has assessed this guideline's adherence to standards of trustworthiness, derived from the Institute of Medicine's report Clinical Practice Guidelines We Can Trust.

= Poor = Fair = Good = Very Good = Excellent

| Assessment | Standard of Trustworthiness |
|---|---|
| YES | Disclosure of Guideline Funding Source |
| | Disclosure and Management of Financial Conflict of Interests |
| | Guideline Development Group Composition |
| YES | Multidisciplinary Group |
| YES | Methodologist Involvement |
| | Patient and Public Perspectives |

| | |
|---|---|
| | Use of a Systematic Review of Evidence |
| ▮▮▮▮▯ | Search Strategy |
| ▮▮▮▮▮ | Study Selection |
| ▮▮▮▮▮ | Synthesis of Evidence |
| | Evidence Foundations for and Rating Strength of Recommendations |
| ▮▮▮▮▮ | Grading the Quality or Strength of Evidence |
| ▮▮▮▮▮ | Benefits and Harms of Recommendations |
| ▮▮▮▮▮ | Evidence Summary Supporting Recommendations |
| ▮▮▮▮▮ | Rating the Strength of Recommendations |
| ▮▮▮▮▮ | Specific and Unambiguous Articulation of Recommendations |
| ▮▮▮▯▯ | External Review |
| ▮▮▮▮▮ | Updating |

# Recommendations

## Major Recommendations

The U.S. Preventive Services Task Force (USPSTF) grades its recommendations (A, B, C, D, or I) and identifies the levels of certainty regarding net benefit (High, Moderate, and Low). The definitions of these grades can be found at the end of the "Major Recommendations" field.

Summary of Recommendation and Evidence

The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of screening for celiac disease in asymptomatic persons (I statement).

Clinical Considerations

Patient Population Under Consideration

This recommendation applies to adults, adolescents, and children who do not have signs or symptoms of celiac disease.

Suggestions for Practice Regarding the I Statement

*Potential Preventable Burden*

Classic celiac disease is associated with symptoms of malabsorption, including diarrhea, abdominal pain, and weight loss. It may also manifest as nonspecific, nongastrointestinal symptoms, including anemia, osteoporosis, chronic fatigue, peripheral neuropathy or ataxia, and short stature. Data from the United States (U.S.) suggest that some patients may have symptoms for years before being diagnosed. Evidence also suggests that celiac disease is associated with excess mortality, intestinal adenocarcinoma, and lymphoma; however, evidence is insufficient as to whether silent, or asymptomatic, disease has the same

risk as symptomatic disease.

In 3 U.S.-based studies, the prevalence of laboratory-confirmed celiac disease ranged from 0.40% to 0.95% among adults. Some variations in prevalence can be attributed in part to the method used to confirm diagnosis. For example, some population-based studies on prevalence rely on serologic testing without histologic confirmation, which may result in false-positive diagnoses and overestimate prevalence. However, in a systematic review of 38 studies from North America and Western Europe, prevalence of celiac disease was similar among studies that included biopsy confirmation (0.15%-1.90%) and among studies that did not include biopsy confirmation (0.15%-2.70%).

Celiac disease affects children, adolescents, and adults. Seroconversion to antibodies associated with celiac disease may occur at any time, and disease progression can take months or years, if it occurs at all. Data suggest that the average age at diagnosis is now in the fourth to sixth decade of life. Data are limited on the proportion of persons with silent celiac disease (positive histology findings but no symptoms) or potential celiac disease (positive serology findings but mild or no intestinal damage on biopsy) who later develop symptomatic celiac disease. Three long-term studies of U.S. adults with follow-up ranging from 10 to 45 years reported rates of progression from positive serology findings to clinical diagnosis of celiac disease of 0% to 15%.

Persons at increased risk for celiac disease include those who have a positive family history (e.g., a first- or second-degree relative), with an estimated prevalence of 5% to 20%, and persons with other autoimmune diseases (e.g., type 1 diabetes mellitus, inflammatory luminal gastrointestinal disorders, Down syndrome, Turner syndrome, immunoglobulin A [IgA] deficiency, and IgA nephropathy). Several specialty societies recommend screening in these populations. Reported prevalence among racial/ethnic minorities is lower than among non-Hispanic whites.

*Potential Harms*

Potential harms of screening for celiac disease in asymptomatic populations include false-positive, inconclusive, or unnecessary serologic test results and biopsies, with possible anxiety or complications from testing. Based on estimated likelihood ratios in the general population, the positive predictive value of serologic testing for celiac disease is 12% to 40%, assuming a prevalence of approximately 1%. In a higher-risk population, the positive predictive value is 40%to 80%, depending on the serologic test used and whether the assumed prevalence is 5% or 10%. Some patients with positive serology findings who do not undergo histologic confirmation may make efforts to avoid dietary gluten, which can increase costs and burdens and may result in limitations on quality of life. Limited evidence from 5 long-term follow-up studies (3 studies of patients with positive serology findings; 2 studies of children with biopsy confirmation) has shown that some persons who are diagnosed with celiac disease may never develop symptoms or complications; thus, overdiagnosis is also a potential concern.

*Current Practice*

Reliable data on the frequency of screening for celiac disease in asymptomatic persons in clinical practice are not available. It is not known how many patients with positive serology findings without biopsy confirmation are treated with a gluten-free diet.

Screening Tests

Screening for celiac disease is typically not performed in average-risk persons. The standard method of diagnosing celiac disease in symptomatic persons older than 2 years is the tissue transglutaminase (tTG) IgA test, followed by intestinal biopsy for histologic confirmation.

Definitions

What the USPSTF Grades Mean and Suggestions for Practice

| Grade | Grade Definitions | Suggestions for Practice |
|---|---|---|
| A | The USPSTF recommends the service. There | Offer or provide this service. |

| Grade | Grade Definitions | Suggestions for Practice |
|---|---|---|
| | is high certainty that the net benefit is substantial. | |
| B | The USPSTF recommends the service. There is high certainty that the net benefit is moderate, or there is moderate certainty that the net benefit is moderate to substantial. | Offer or provide this service. |
| C | The USPSTF recommends selectively offering or providing this service to individual patients based on professional judgment and patient preferences. There is at least moderate certainty that the net benefit is small. | Offer or provide this service for selected patients depending on individual circumstances. |
| D | The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits. | Discourage the use of this service. |
| I Statement | The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality or conflicting, and the balance of benefits and harms cannot be determined. | Read the "Clinical Considerations" section of the USPSTF Recommendation Statement (see the "Major Recommendations" field). If offered, patients should understand the uncertainty about the balance of benefits and harms. |

USPSTF Levels of Certainty Regarding Net Benefit

Definition: The USPSTF defines certainty as "likelihood that the USPSTF assessment of the net benefit of a preventive service is correct." The net benefit is defined as benefit minus harm of the preventive service as implemented in a general, primary care population. The USPSTF assigns a certainty level based on the nature of the overall evidence available to assess the net benefit of a preventive service.

| Level of Certainty | Description |
|---|---|
| High | The available evidence usually includes consistent results from well-designed, well-conducted studies in representative primary care populations. These studies assess the effects of the preventive service on health outcomes. This conclusion is therefore unlikely to be strongly affected by the results of future studies. |
| Moderate | The available evidence is sufficient to determine the effects of the preventive service on health outcomes, but confidence in the estimate is constrained by factors such as:<br><br>The number, size, or quality of individual studies<br>Inconsistency of findings across individual studies<br>Limited generalizability of findings to routine primary care practice<br>Lack of coherence in the chain of evidence<br><br>As more information becomes available, the magnitude or direction of the observed effect could change, and this change may be large enough to alter the conclusion. |
| Low | The available evidence is insufficient to assess effects on health outcomes. Evidence is insufficient because of:<br><br>The limited number or size of studies<br>Important flaws in study design or methods<br>Inconsistency of findings across individual studies<br>Gaps in the chain of evidence<br>Findings not generalizable to routine primary care practice<br>A lack of information on important health outcomes<br><br>More information may allow an estimation of effects on health outcomes. |

## Clinical Algorithm(s)

None provided

# Scope

## Disease/Condition(s)

Celiac disease

## Guideline Category

Screening

## Clinical Specialty

Family Practice

Gastroenterology

Internal Medicine

Pediatrics

## Intended Users

Advanced Practice Nurses

Allied Health Personnel

Health Care Providers

Nurses

Physician Assistants

Physicians

## Guideline Objective(s)

To issue a new U.S. Preventive Services Task Force (USPSTF) recommendation on screening for celiac disease

## Target Population

Adults, adolescents, and children who do not have signs or symptoms of celiac disease

## Interventions and Practices Considered

Screening for celiac disease

## Major Outcomes Considered

- Key Question 1: What is the effectiveness of screening vs. not screening for celiac disease in asymptomatic adults, adolescents, or children on morbidity, mortality, or quality of life?
- Key Question 2: What is the effectiveness of targeted vs. universal screening for celiac disease in

asymptomatic adults, adolescents, or children on morbidity, mortality, or quality of life? (Targeted screening refers to testing in patients with family history or other risk factors for celiac disease.)
- Key Question 3: What are the harms of screening for celiac disease?
- Key Question 4: What is the accuracy of screening tests for celiac disease?
- Key Question 5: Does treatment of screen-detected celiac disease lead to improved morbidity, mortality, or quality of life compared with no treatment?
- Key Question 6: Does treatment of screen-detected celiac disease lead to improved morbidity, mortality, or quality of life compared with treatment initiated after clinical diagnosis?
- Key Question 7: What are the harms associated with treatment of celiac disease?

# Methodology

## Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

## Description of Methods Used to Collect/Select the Evidence

Note from the National Guideline Clearinghouse (NGC): A systematic evidence review was prepared by the Pacific Northwest Evidence-based Practice Center (EPC) for use by the U.S. Preventive Services Task Force (USPSTF) (see the "Availability of Companion Documents" field).

Data Sources and Searches

The Cochrane Central Register of Controlled Trials, Cochrane Database of Systematic Reviews, and Ovid MEDLINE databases were searched from 1991, 2005, and 1946, respectively, to June 14, 2016, for relevant studies and systematic reviews. The search strategies are listed in the eMethods in the systematic review supplement. Reference lists of relevant articles were also reviewed.

Study Selection

Two reviewers independently evaluated each study to determine inclusion eligibility. Studies were selected on the basis of inclusion and exclusion criteria developed for each key question (KQ). For screening and diagnosis, the population of interest was asymptomatic adults, adolescents, or children 3 years or older without known celiac disease who had not sought evaluation for possible celiac disease. The population included persons at higher risk because of family history or presence of conditions associated with celiac disease, such as type 1 diabetes mellitus, autoimmune thyroiditis, or Down syndrome, as well as persons not known to be at higher risk. For treatment, the population of interest was asymptomatic persons with screen-detected celiac disease. Studies of mildly symptomatic patients were also included if no studies were available in asymptomatic populations.

Screening tests were serologic tests or questionnaires. Included were randomized trials, cohort studies, and case-control studies performed in primary care or primary care–applicable settings of screening vs. no screening, targeted vs. universal screening, treatment vs. no treatment, and immediate vs. delayed treatment that reported morbidity (including clinical outcomes related to nutritional deficiencies and gastrointestinal symptoms), cancer incidence, mood and anxiety, child growth outcomes, infection rates, quality of life, mortality, or harms associated with screening or treatment. For diagnostic accuracy, cohort and cross-sectional studies that compared screening tests against intestinal biopsy as the reference standard were included. The Marsh classification system categorizes biopsy findings based on the presence of intraepithelial lymphocytosis (Marsh 1 or greater), crypt hyperplasia (Marsh 2 or greater), and villous atrophy (Marsh 3 or greater). The presence of villous atrophy (Marsh 3 or 4) is considered the

hallmark of celiac disease, with Marsh 1 and 2 more equivocal.

Studies reporting only intermediate outcomes such as laboratory values for nutritional or other deficiencies and studies that evaluated diagnostic accuracy using a case-control design were excluded. To summarize the diagnostic accuracy of screening tests in populations not restricted to asymptomatic persons, good-quality systematic reviews published since 2015 were also included. The selection of literature is summarized in the literature flow diagram (see Figure 2 in the systematic review).

## Number of Source Documents

See the literature search flow diagram (Figure 2) in the systematic review (see the "Availability of Companion Documents" field) for a summary of evidence search and selection.

Articles included for Key Questions:

- Key Question 1: 0 studies
- Key Question 2: 0 studies
- Key Question 3: 0 studies
- Key Question 4: 3 studies (1 systematic review and 2 primary studies)
- Key Question 5: 1 study
- Key Question 6: 0 study
- Key Question 7: 1 study

## Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

## Rating Scheme for the Strength of the Evidence

Two investigators independently applied criteria developed by the U.S. Preventive Services Task Force (USPSTF) to rate the quality of each study as good, fair, or poor. The quality assessment criteria are reported in the eMethods in the systematic review supplement (see the "Availability of Companion Documents" field). Discrepancies were resolved through consensus.

## Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

## Description of the Methods Used to Analyze the Evidence

Note from the National Guideline Clearinghouse (NGC): A systematic evidence review was prepared by the Pacific Northwest Evidence-based Practice Center (EPC) for use by the U.S. Preventive Services Task Force (USPSTF) (see the "Availability of Companion Documents" field).

Data Extraction and Quality Assessment

One investigator extracted details about each article's study design, patient population, setting, screening method, treatment regimen, analysis, follow-up, and results. A second investigator reviewed data abstraction for accuracy. Two investigators independently applied criteria developed by the USPSTF to rate the quality of each study as good, fair, or poor. The quality assessment criteria are reported in the eMethods in the systematic review supplement. Discrepancies were resolved through consensus.

Data Synthesis and Analysis

The aggregate internal validity (quality) of the body of evidence for each key question (KQ) (good, fair, poor) was assessed using methods developed by the USPSTF, based on the number, quality, and size of studies; consistency of results between studies; and directness of evidence. There were too few studies to perform meta-analysis.

## Methods Used to Formulate the Recommendations

Balance Sheets

Expert Consensus

## Description of Methods Used to Formulate the Recommendations

The U.S. Preventive Services Task Force (USPSTF) systematically reviews the evidence concerning both the benefits and harms of widespread implementation of a preventive service. It then assesses the certainty of the evidence and the magnitude of the benefits and harms. On the basis of this assessment, the USPSTF assigns a letter grade to each preventive service signifying its recommendation about provision of the service (see table below). An important, but often challenging, step is determining the balance between benefits and harms to estimate "net benefit" (that is, benefits minus harms).

U.S. Preventive Services Task Force Recommendation Grid*

| Certainty of Net Benefit | Magnitude of Net Benefit | | | |
|---|---|---|---|---|
| | Substantial | Moderate | Small | Zero/Negative |
| High | A | B | C | D |
| Moderate | B | B | C | D |
| Low | Insufficient | | | |

**A*, *B*, *C*, *D*, and *I (Insufficient)* represent the letter grades of recommendation or statement of insufficient evidence assigned by the USPSTF after assessing certainty and magnitude of net benefit of the service (see the "Rating Scheme for the Strength of the Recommendations" field).

The overarching question that the USPSTF seeks to answer for every preventive service is whether evidence suggests that provision of the service would improve health outcomes if implemented in a general primary care population. For screening topics, this standard could be met by a large randomized controlled trial (RCT) in a representative asymptomatic population with follow-up of all members of both the group "invited for screening" and the group "not invited for screening."

Direct RCT evidence about screening is often unavailable, so the USPSTF considers indirect evidence. To guide its selection of indirect evidence, the USPSTF constructs a "chain of evidence" within an analytic framework. For each key question, the body of pertinent literature is critically appraised, focusing on the following 6 questions:

Do the studies have the appropriate research design to answer the key question(s)?
To what extent are the existing studies of high quality? (i.e., what is the internal validity?)
To what extent are the results of the studies generalizable to the general U.S. primary care population and situation? (i.e., what is the external validity?)
How many studies have been conducted that address the key question(s)? How large are the studies? (i.e., what is the precision of the evidence?)
How consistent are the results of the studies?
Are there additional factors that assist the USPSTF in drawing conclusions (e.g., presence or absence of dose–response effects, fit within a biologic model)?

The next step in the USPSTF process is to use the evidence from the key questions to assess whether there would be net benefit if the service were implemented. In 2001, the USPSTF published an article that documented its systematic processes of evidence evaluation and recommendation development. At that time, the USPSTF's overall assessment of evidence was described as good, fair, or poor. The USPSTF realized that this rating seemed to apply only to how well studies were conducted and did not fully capture all of the issues that go into an overall assessment of the evidence about net benefit. To avoid confusion, the USPSTF has changed its terminology. Whereas individual study quality will continue to be characterized as good, fair, or poor, the term *certainty* will now be used to describe the USPSTF's assessment of the overall body of evidence about net benefit of a preventive service and the likelihood that the assessment is correct. Certainty will be determined by considering all 6 questions listed above; the judgment about certainty will be described as high, moderate, or low.

In making its assessment of certainty about net benefit, the evaluation of the evidence from each key question plays a primary role. It is important to note that the USPSTF makes recommendations for real-world medical practice in the United States and must determine to what extent the evidence for each key question—even evidence from screening RCTs or treatment RCTs—can be applied to the general primary care population. Frequently, studies are conducted in highly selected populations under special conditions. The USPSTF must consider differences between the general primary care population and the populations studied in RCTs and make judgments about the likelihood of observing the same effect in actual practice.

It is also important to note that one of the key questions in the analytic framework refers to the potential harms of the preventive service. The USPSTF considers the evidence about the benefits and harms of preventive services separately and equally. Data about harms are often obtained from observational studies because harms observed in RCTs may not be representative of those found in usual practice and because some harms are not completely measured and reported in RCTs.

Putting the body of evidence for all key questions together as a chain, the USPSTF assesses the certainty of net benefit of a preventive service by asking the 6 major questions listed above. The USPSTF would rate a body of convincing evidence about the benefits of a service that, for example, derives from several RCTs of screening in which the estimate of benefits can be generalized to the general primary care population as "high" certainty (see the "Rating Scheme for the Strength of Recommendations" field). The USPSTF would rate a body of evidence that was not clearly applicable to general practice or has other defects in quality, research design, or consistency of studies as "moderate" certainty. Certainty is "low" when, for example, there are gaps in the evidence linking parts of the analytic framework, when evidence to determine the harms of treatment is unavailable, or when evidence about the benefits of treatment is insufficient. Table 4 in the methodology document listed below (see the "Availability of Companion Documents" field) summarizes the current terminology used by the USPSTF to describe the critical assessment of evidence at all 3 levels: individual studies, key questions, and overall certainty of net benefit of the preventive service.

Sawaya GF, Guirguis-Blake J, LeFevre M, Harris R, Petitti D; U.S. Preventive Services Task Force. Update on the methods of the U.S. Preventive Services Task Force: estimating certainty and magnitude of net benefit. Ann Intern Med. 2007;147:871-5. [5 references].

I Statements

For I statements, the USPSTF has a plan to commission its Evidence-based Practice Centers (EPCs) to collect information in 4 domains pertinent to clinical decisions about prevention and to report this information routinely. This plan is described in the paper: Petitti DB et al. Update on the methods of the U.S. Preventive Services Task Force: insufficient evidence. Ann Intern Med. 2009;150:199-205. www.annals.org

The first domain is potential preventable burden of suffering from the condition. When evidence is insufficient, provision of an intervention designed to prevent a serious condition (such as dementia) might be viewed more favorably than provision of a service designed to prevent a condition that does not cause as much suffering (such as rash). The USPSTF recognized that "burden of suffering" is subjective

and involves judgment. In clinical settings, it should be informed by patient values and concerns.

The second domain is potential harm of the intervention. When evidence is insufficient, an intervention with a large potential for harm (such as major surgery) might be viewed less favorably than an intervention with a small potential for harm (such as advice to watch less television). The USPSTF again acknowledges the subjective nature and the difficulty of assessing potential harms: for example, how bad is a "mild" stroke?

The third domain is cost—not just monetary cost, but opportunity cost, in particular the amount of time a provider spends to provide the service, the amount of time the patient spends to partake of it, and the benefits that might derive from alternative uses of the time or money for patients, clinicians, or systems. Consideration of clinician time is especially important for preventive services with only insufficient evidence because providing them could "crowd out" provision of preventive services with proven value, services for conditions that require immediate action, or services more desired by the patient. For example, a decision to routinely inspect the skin could take up the time available to discuss smoking cessation, or to address an acute problem or a minor injury that the patient considers important.

The fourth domain is current practice. This domain was chosen because it is important to clinicians for at least 2 reasons. Clinicians justifiably fear that not doing something that is done on a widespread basis in the community may lead to litigation. More important, addressing patient expectations is a crucial part of the clinician–patient relationship in terms of building trust and developing a collaborative therapeutic relationship. The consequences of not providing a service that is neither widely available nor widely used are less serious than not providing a service accepted by the medical profession and thus expected by patients. Furthermore, ingrained care practices are difficult to change, and efforts should preferentially be directed to changing those practices for which the evidence to support change is compelling.

Although the reviewers did not explicitly recognize it when these domains were chosen, the domains all involve consideration of the potential consequences—for patients, clinicians, and systems—of providing or not providing a service. Others writing about medical decision making in the face of uncertainty have suggested that the consequences of action or inaction should play a prominent role in decisions.

## Rating Scheme for the Strength of the Recommendations

What the U.S. Preventive Services Task Force (USPSTF) Grades Mean and Suggestions for Practice

| Grade | Grade Definitions | Suggestions for Practice |
|---|---|---|
| A | The USPSTF recommends the service. There is high certainty that the net benefit is substantial. | Offer or provide this service. |
| B | The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial. | Offer or provide this service. |
| C | The USPSTF recommends selectively offering or providing this service to individual patients based on professional judgment and patient preferences. There is at least moderate certainty that the net benefit is small. | Offer or provide this for selected patients depending on individual circumstances. |
| D | The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits. | Discourage the use of this service. |
| I Statement | The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality | Read the "Clinical Considerations" section of the USPSTF Recommendation Statement (see the "Major Recommendations" field). If the service is offered, patients should |

| Grade | Grade Definitions | Suggestions for Practice |
|---|---|---|
| | or conflicting, and the balance of benefits and harms cannot be determined. | understand the uncertainty about the balance of benefits and harms. |

USPSTF Levels of Certainty Regarding Net Benefit

Definition: The USPSTF defines certainty as "likelihood that the USPSTF assessment of the net benefit of a preventive service is correct." The net benefit is defined as benefit minus harm of the preventive service as implemented in a general, primary care population. The USPSTF assigns a certainty level based on the nature of the overall evidence available to assess the net benefit of a preventive service.

| Level of Certainty | Description |
|---|---|
| High | The available evidence usually includes consistent results from well-designed, well-conducted studies in representative primary care populations. These studies assess the effects of the preventive service on health outcomes. This conclusion is therefore unlikely to be strongly affected by the results of future studies. |
| Moderate | The available evidence is sufficient to determine the effects of the preventive service on health outcomes, but confidence in the estimate is constrained by factors such as:<br><br>The number, size, or quality of individual studies<br>Inconsistency of findings across individual studies<br>Limited generalizability of findings to routine primary care practice<br>Lack of coherence in the chain of evidence<br><br>As more information becomes available, the magnitude or direction of the observed effect could change, and this change may be large enough to alter the conclusion. |
| Low | The available evidence is insufficient to assess effects on health outcomes. Evidence is insufficient because of:<br><br>The limited number or size of studies<br>Important flaws in study design or methods<br>Inconsistency of findings across individual studies<br>Gaps in the chain of evidence<br>Findings not generalizable to routine primary care practice<br>A lack of information on important health outcomes<br><br>More information may allow an estimation of effects on health outcomes. |

## Cost Analysis

The U.S. Preventive Services Task Force (USPSTF) does not consider the costs of providing a service in its assessment.

## Method of Guideline Validation

Comparison with Guidelines from Other Groups

External Peer Review

Internal Peer Review

## Description of Method of Guideline Validation

Peer Review

Before the U.S. Preventive Services Task Force (USPSTF) makes its final determinations about recommendations on a given preventive service, the Evidence-based Practice Center (EPC) and the Agency for Healthcare Research and Quality (AHRQ) send the draft evidence review to 4 to 6 external experts and to Federal agencies and professional and disease-based health organizations with interests in the topic.

The experts are asked to examine the review critically for accuracy and completeness and to respond to a series of specific questions about the document. The draft evidence review is also posted on the USPSTF Web site for public comment. After assembling these external review comments and documenting the proposed response to key comments, the topic team presents this information to the USPSTF in memo form. In this way, the USPSTF can consider these external comments before it votes on its recommendations about the service. Draft recommendation statements are then circulated for comment among reviewers representing professional societies, voluntary organizations, and Federal agencies, as well as posted on the USPSTF Web site for public comment. These comments are discussed before the final recommendations are confirmed.

Response to Public Comment

A draft version of this recommendation statement was posted for public comment on the USPSTF Web site from May 3 to May 30, 2016. Many comments described patients' personal experience of a delayed diagnosis because of atypical or nonspecific symptoms. In response, the USPSTF expanded the "Suggestions for Practice" section to call attention to the prevalence of nonclassical symptoms, including anemia and osteoporosis, and delayed diagnosis. Another frequently raised concern was the higher risk among relatives of patients with celiac disease and patients with other autoimmune diseases. The USPSTF revised the "Research Needs and Gaps" section to emphasize the importance of developing evidence to guide clinical practice for this population.

Comparison with Guidelines from Other Groups

Recommendations for screening from the following groups were discussed: the American Academy of Family Physicians, the American College of Gastroenterology, the National Institute for Health and Care Excellence, and the North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition.

# Evidence Supporting the Recommendations

## Type of Evidence Supporting the Recommendations

The type of evidence supporting the recommendations is not specifically stated.

# Benefits/Harms of Implementing the Guideline Recommendations

## Potential Benefits

Benefits of Early Detection and Intervention or Treatment

The U.S. Preventive Services Task Force (USPSTF) found inadequate evidence on the effectiveness of screening for celiac disease in asymptomatic adults, adolescents, and children with regard to morbidity, mortality, or quality of life. The USPSTF also found inadequate evidence on the effectiveness of targeted screening in persons who are at increased risk for celiac disease (e.g., persons with family history or other risk factors).

The USPSTF found inadequate evidence on the effectiveness of treatment of screen-detected, asymptomatic celiac disease to improve morbidity, mortality, or quality of life compared with no treatment or treatment initiated after clinical diagnosis.

## Potential Harms

Harms of Early Detection and Intervention or Treatment

The U.S. Preventive Services Task Force (USPSTF) found inadequate evidence on the harms of screening for or treatment of celiac disease.

# Qualifying Statements

## Qualifying Statements

- The U.S. Preventive Services Task Force (USPSTF) makes recommendations about the effectiveness of specific clinical preventive services for patients without obvious related signs or symptoms.
- It bases its recommendations on the evidence of both the benefits and harms of the service and an assessment of the balance. The USPSTF does not consider the costs of providing a service in this assessment.
- The USPSTF recognizes that clinical decisions involve more considerations than evidence alone. Clinicians should understand the evidence but individualize decision making to the specific patient or situation. Similarly, the USPSTF notes that policy and coverage decisions involve considerations in addition to the evidence of clinical benefits and harms.
- Recommendations made by the USPSTF are independent of the U.S. government. They should not be construed as an ofï¬cial position of the Agency for Healthcare Research and Quality (AHRQ) or the U.S. Department of Health and Human Services (DHHS).

# Implementation of the Guideline

## Description of Implementation Strategy

The experiences of the first and second U.S. Preventive Services Task Force (USPSTF), as well as that of other evidence-based guideline efforts, have highlighted the importance of identifying effective ways to implement clinical recommendations. Practice guidelines are relatively weak tools for changing clinical practice when used in isolation. To effect change, guidelines must be coupled with strategies to improve their acceptance and feasibility. Such strategies include enlisting the support of local opinion leaders, using reminder systems for clinicians and patients, adopting standing orders, and audit and feedback of information to clinicians about their compliance with recommended practice.

In the case of preventive services guidelines, implementation needs to go beyond traditional dissemination and promotion efforts to recognize the added patient and clinician barriers that affect preventive care. These include clinicians' ambivalence about whether preventive medicine is part of their job, the psychological and practical challenges that patients face in changing behaviors, lack of access to health care or of insurance coverage for preventive services for some patients, competing pressures within the context of shorter office visits, and the lack of organized systems in most practices to ensure the delivery of recommended preventive care.

Dissemination strategies have changed dramatically in this age of electronic information. While recognizing the continuing value of journals and other print formats for dissemination, the USPSTF will make all its products available through its Web site . The combination of electronic access and extensive material in the public domain should make it easier for a broad audience of users to access USPSTF materials and adapt them for their local needs. Online access to USPSTF products also opens up new possibilities for the appearance of the annual, pocket-size *Guide to Clinical Preventive Services*.

To be successful, approaches for implementing prevention have to be tailored to the local level and deal with the specific barriers at a given site, typically requiring the redesign of systems of care. Such a

systems approach to prevention has had notable success in established staff-model health maintenance organizations, by addressing organization of care, emphasizing a philosophy of prevention, and altering the training and incentives for clinicians. Staff-model plans also benefit from integrated information systems that can track the use of needed services and generate automatic reminders aimed at patients and clinicians, some of the most consistently successful interventions. Information systems remain a major challenge for individual clinicians' offices, however, as well as for looser affiliations of practices in network-model managed care and independent practice associations, where data on patient visits, referrals, and test results are not always centralized.

### Implementation Tools

Mobile Device Resources

Patient Resources

Pocket Guide/Reference Cards

Staff Training/Competency Material

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

## Institute of Medicine (IOM) National Healthcare Quality Report Categories

### IOM Care Need

Staying Healthy

### IOM Domain

Effectiveness

Patient-centeredness

## Identifying Information and Availability

### Bibliographic Source(s)

Final recommendation statement: celiac disease: screening. [internet]. Rockville (MD): U.S. Preventive Services Task Force (USPSTF); 2017 Mar [7 p]. [28 references]

### Adaptation

Not applicable: The guideline was not adapted from another source.

### Date Released

2017 Mar

## Guideline Developer(s)

U.S. Preventive Services Task Force - Independent Expert Panel

## Guideline Developer Comment

The U.S. Preventive Services Task Force (USPSTF) is a federally-appointed panel of independent experts. Conclusions of the USPSTF do not necessarily reflect policy of the U.S. Department of Health and Human Services or its agencies.

## Source(s) of Funding

The U.S. Preventive Services Task Force (USPSTF) is an independent, voluntary body. The U.S. Congress mandates that the Agency for Healthcare Research and Quality (AHRQ) support the operations of the USPSTF.

## Guideline Committee

U.S. Preventive Services Task Force (USPSTF)

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*Members of the Task Force at the time this recommendation was finalized. For a list of current Task Force members, go to https://www.uspreventiveservicestaskforce.org/Page/Name/our-members.

## Financial Disclosures/Conflicts of Interest

The U.S. Preventive Services Task Force (USPSTF) has an explicit policy concerning conflict of interest. All members disclose at each meeting if they have a significant financial, professional/business, or intellectual conflict for each topic being discussed. USPSTF members with conflicts may be recused from discussing or voting on recommendations about the topic in question.

Conflict of Interest Disclosures

All authors have completed and submitted the International Committee of Medical Journal Editors (ICMJE) Form for Disclosure of Potential Conflicts of Interest. Authors followed the policy regarding conflicts of interest described at https://www.uspreventiveservicestaskforce.org/Page/Name/conflict-of-interest-disclosures. All members of the USPSTF receive travel reimbursement and an

honorarium for participating in USPSTF meetings.

## Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

## Guideline Availability

Available from the U.S. Preventive Services Task Force (USPSTF) Web site .

## Availability of Companion Documents

The following are available:

Evidence Reviews:

> Chou R, Bougatsos C, Blazina I, Mackey K, Grusing S, Selph S. Screening for celiac disease: evidence report and systematic review for the U.S. Preventive Services Task Force. JAMA. 2017 Mar 28;317(12)1258-68.
> Chou R, Bougatsos C, Blazina I, Mackey K, Grusing S, Selph S. Screening for celiac disease: a systematic review for the U.S. Preventive Services Task Force. Evidence Synthesis No. 144. AHRQ Publication No. 14-05215-EF-1. Rockville (MD): Agency for Healthcare Research and Quality; 2017 Mar. 60 p.

Available from the U.S. Preventive Services Task Force (USPSTF) Web site .

The following are also available:

> Celiac disease: screening. Clinical summary. Rockville (MD): Agency for Healthcare Research and Quality; 2017 Mar. 1 p. Available from the USPSTF Web site .

The Electronic Preventive Services Selector (ePSS) is an application designed to provide primary care clinicians and health care teams timely decision support regarding appropriate screening, counseling, and preventive services for their patients. It is based on the current, evidence-based recommendations of the USPSTF and can be searched by specific patient characteristics, such as age, sex, and selected behavioral risk factors.

## Patient Resources

The following is available:

> Screening for celiac disease. JAMA patient page. 2017 Mar 28;317(12):1286.

Myhealthfinder is a tool that provides personalized recommendations for clinical preventive services specific to the user's age, gender, and pregnancy status. It features evidence-based recommendations from the USPSTF and is available at www.healthfinder.gov .

## NGC Status

This NGC summary was completed by ECRI Institute on May 12, 2017. The information was verified by the guideline developer on May 17, 2017.

This NEATS assessment was completed by ECRI Institute on June 22, 2017. The information was verified by the guideline developer on July 3, 2017.

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